The draft PTC document is different from, although similar in format and topics to, the PTC document entitled "Points to Consider in the Manufacture of In Vitro Monoclonal Antibody Products Subject to Licensure," which is dated June 1983, and was prepared by the Office of Biologics, National Center for Drugs and Biologics (now CBER), FDA. This latter PTC document remains both available and relevant to diagnostic substances for laboratory tests, other than Blood Grouping Reagent and Anti-Human Globulin.

Interested persons may submit written comments on the draft PTC document to the Dockets Management Branch (address above). Such comments received will be considered in determining whether further revision of the draft PTC document is warranted.

Dated: April 24, 1992.

Michael R. Taylor,

Deputy Commissioner of Policy.

[FR Doc. 92-10135 Filed 4-30-92; 8:45 am]

BILLING CODE 4160-01-M

[Docket No. 92N-0192]

Environmental Assessments and Findings of No Significant Impact

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that it has received environmental assessments (EA's) and issued findings of no significant impact (FONSI's) relating to the approval of new drug applications (NDA's) for the following products: Ceredase (glucocerebrosidase); Ergamisol (levamisole hydrochloride) Tablets; Exosurf (colfosceril palmitate) Pediatric Sterile Powder; Foscavir (foscarnet sodium) Injection; Nipent (pentostatin); Survanta (beractant); TechneScan MAG3, a kit containing betiatide for the preparation of technetium Tc 99m mertiatide; Videx (didanosine) Chewable Tablets; Buffered Powder for Oral Solution; and Pediatric Powder for Oral Solution. FDA is publishing this notice under section 102 of the National Environmental Policy Act (42 U.S.C. 4332), 21 CFR 25.41(b), and 40 CFR 1506.6.

ADDRESSES: The EA's and FONSI's may be seen in the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Philip L. Chao, Center for Drug Evaluation and Research (HFD-362), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-295-8049.

SUPPLEMENTARY INFORMATION: The National Environmental Policy Act (NEPA) requires all Federal agencies to "use all practicable means and measures, including financial and technical assistance, in a manner calculated to foster and promote the general welfare, to create and maintain conditions under which man and nature can exist in productive harmony, and fulfill the social, economic, and other requirements of present and future generations of Americans." (See 42 U.S.C. 4331(a).) Under NEPA, all Federal agencies must prepare detailed statements assessing the possible environmental impact of, and alternatives to, major Federal actions significantly affecting the environment, and such statements are to be made available to the public. (See 42 U.S.C. 4332, 40 CFR 1506.6, and 21 CFR 25.41(b).)

FDA implements NEPA through its regulations at 21 CFR Part 25. Under those regulations, the approval of an NDA usually constitutes an action that ordinarily requires the preparation of an EA. (See 21 CFR 25.22(a)(14).)

FDA recently approved NDA's pertaining to the following products: Ceredase (glucocerebrosidase), NDA 20-057; Ergamisol (levamisole hydrochloride) Tablets, NDA 20-035; Exosurf (colfosceril palmitate) Pediatric Sterile Powder, NDA 20-044; Foscavir (foscarnet sodium) Injection, NDA 20-068; Nipent (pentostatin), NDA 20-122; Survanta (beractant), NDA 20-032; TechneScan MAG3, a kit containing betiatide for the preparation of technetium Tc 99m mertiatide, NDA 19-882; Videx (didanosine) Chewable Tablets, NDA 20-154; Buffered Powder for Oral Solution, NDA 20-155; and Pediatric Powder for Oral Solution, NDA 20-156.

The agency has reviewed the EA's submitted for each NDA and prepared a FONSI for each. No environmental impact statements, therefore, are necessary. This notice announces that the EA's and FONSI's for these human drug products may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 23, 1992.

Michael R. Taylor,

Deputy Commissioner for Policy.

[FR Doc. 92-10188 Filed 4-30-92; 8:45 am]

BILLING CODE 4160-01-F

[Docket No. 92E-0115]

Determination of Regulatory Review Period for Purposes of Patent Extension; Acel-Imune®

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for Acel-Imune® and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

ADDRESSES: Written comments and petitions should be directed to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Brian J. Malkin, Office of Health Affairs (HFY-20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-1382.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100-670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: a testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Commissioner of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was

issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product, Acel-Imune®. Acel-Imune® (Diphtheria and Tetanus Toxoids and Acellular Pertussis Vaccine Adsorbed (DTP)) is indicated as a fourth and/or fifth dose for children from 17 months of age up to age 7 years (prior to 7th birthday) who have previously been immunized against diphtheria, tetanus, and pertussis with three or four doses of whole-cell DTP vaccine. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for Acel-Imune® (U.S. Patent No. 4,455,297) from the Takeda Chemical Industries, Ltd., and the Patent and Trademark Office requested FDA's assistance in determining the patent's eligibility for patent term restoration. FDA, in a letter dated April 6, 1992, advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of Acel-Imune® represented the first commercial marketing of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for Acel-Imune® is 2,002 days. Of this time, 400 days occurred during the testing phase of the regulatory review period, while 1,602 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act became effective: June 24, 1986. FDA has verified the applicant's claim that the date the investigational new drug application became effective was June 24, 1986.

2. The date the application was initially submitted with respect to the human drug product under section 351 of the Public Health Service Act: September 1, 1987. FDA has verified the applicant's claim that the product license application (PLA) for Acel-Imune® (PLA 87-0406) became effective on September 1, 1987.

3. The date the application was approved: December 17, 1991. FDA has verified the applicant's claim that PLA 87-0406 was approved on December 17, 1991.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,643 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before June 30, 1992, submit to the Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before October 28, 1992, for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, Part 1, 98th Cong., 2d sess., pp. 41-42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Dockets Management Branch (address above) in three copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 24, 1992.

Stuart L. Nightingale,

Associate Commissioner for Health Affairs.

[FR Doc. 92-10141 Filed 4-30-92; 8:45 am]

BILLING CODE 4160-01-F

[Docket No. 92E-0131]

Determination of Regulatory Review Period for Purposes of Patent Extension; Maxaquin®

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for Maxaquin® and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

ADDRESSES: Written comments and petitions should be directed to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Richard Klein, Office of Health Affairs (HFY-20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-1382.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100-670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: a testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Commissioner of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product Maxaquin®. Maxaquin® (lomefloxacin hydrochloride) is indicated for urinary tract infections and lower respiratory tract infections. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for Maxaquin® (U.S. Patent No. 4,528,287) from Hokuriku Pharmaceutical Co., Ltd., and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. FDA, in a letter dated March 25, 1992, advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of Maxaquin® represented the first commercial marketing of the product. Shortly